

Notice of Allowability

Application No.

10/659,091

Examiner

Eric S. Olson

Applicant(s)

OLD ET AL.

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's amendment submitted November 15, 2006.
2. ☒ The allowed claim(s) is/are 1-22.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 426/05, 9/9/2003
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 20061214A
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

SAJ 12/21/06
SHAOJIA ANNA JIANG, PH.D.
SUPERVISORY PATENT EXAMINER

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Claims 1, 13, 21, and 22 are amended as follows:

Claim 1: Replace the phrase, "wherein a wavy segments indicate either the \square or \square configuration," with, "wherein a the wavy segments indicate either the $\square \alpha$ or $\square \beta$ configuration."

Claim 13: Replace the phrase, "wherein a wavy segments indicate either the \square or \square configuration," with, "wherein a the wavy segments indicate either the $\square \alpha$ or $\square \beta$ configuration."

21. (Currently Amended) The method of claim 1 wherein said compound is selected from the group consisting of

~~(Z)-7-((1R,2S,3R)-2-Butylcarbamoyloxymethyl-3-hydroxy-5-oxo-cyclopentyl)-hept-5-enoic acid methyl ester~~

Art Unit: 1623

~~(Z)-7-((1 R,2S,3R)-2-Butylcarbamoyloxymethyl-3-hydroxy-5-oxo-cyclopentyl)-
hept-5-enoic acid~~

(Z)-7-((1 R,2S,3R,5R)-2-Butylcarbamoyloxymethyl-5-chloro-3-hydroxy-
cyclopentyl)-hept-5-enoic acid methyl ester

(Z)-7-((1 R,2S,3R,5R)-2-Butylcarbamoyloxymethyl-5-chloro-3-hydroxy-
cyclopentyl)-hept-5-enoic acid

~~(Z)-7-((1 R,2S,3R)-3-Hydroxy-5-oxo-2-phenethylcarbamoyloxymethyl-
cyclopentyl)-hept-5-enoic acid methyl ester~~

~~(Z)-7-((1 R,2S,3R)-3-Hydroxy-5-oxo-2-phenethylcarbamoyloxymethyl-
cyclopentyl)-hept-5-enoic acid~~

(Z)-7-((1 R,2S,3R)-2-Butylthiocarbamoyloxymethyl-3-hydroxy-5-oxo-
cyclopentyl)-hept-5-enoic acid methyl ester

(Z)-7-((1 R,2S,3R)-2-Butylthiocarbamoyloxymethyl-3-hydroxy-5-oxo-
cyclopentyl)-hept-5-enoic acid.

Art Unit: 1623

22. (Currently Amended) The compound of claim 13 wherein said compound is selected from the group consisting of

~~(Z)-7-((1R,2S,3R)-2-Butylcarbamoyloxymethyl-3-hydroxy-5-oxo-cyclopentyl)-hept-5-enoic acid methyl ester~~

~~(Z)-7-((1R,2S,3R)-2-Butylcarbamoyloxymethyl-3-hydroxy-5-oxo-cyclopentyl)-hept-5-enoic acid~~

(Z)-7-((1R,2S,3R,5R)-2-Butylcarbamoyloxymethyl-5-chloro-3-hydroxy-cyclopentyl)-hept-5-enoic acid methyl ester

(Z)-7-((1R,2S,3R,5R)-2-Butylcarbamoyloxymethyl-5-chloro-3-hydroxy-cyclopentyl)-hept-5-enoic acid

~~(Z)-7-((1R,2S,3R)-3-Hydroxy-5-oxo-2-phenethylcarbamoyloxymethyl-cyclopentyl)-hept-5-enoic acid methyl ester~~

~~(Z)-7-((1R,2S,3R)-3-Hydroxy-5-oxo-2-phenethylcarbamoyloxymethyl-cyclopentyl)-hept-5-enoic acid~~

Art Unit: 1623

~~(Z)-7-((1R,2S,3R)-2-butylthiocarbamoyloxymethyl-3-hydroxy-5-oxo-cyclopentyl)-hept-5-enoic acid methyl ester~~

~~(Z)-7-((1R,2S,3R)-2-butylthiocarbamoyloxymethyl-3-hydroxy-5-oxo-cyclopentyl)-hept-5-enoic acid.~~

Authorization for this examiner's amendment was given in a telephone interview with Brent Johnson on December 13, 2006.

Detailed Action

This application was filed on September 9, 2003. Claims 1-22 are pending in this application and examined on the merits herein.

Applicants amendment submitted November 15, 2006 with respect to the rejection of claims 1-8 and 13-22 under 35 USC 103 as being unpatentable over Burk in view of Bito, of record in the previous office action, has been fully considered and found to be persuasive to remove the rejection as the ketone species which were found to be obvious over Burk in view of Bito are no longer included within the scope of the claims as amended. Therefore the rejection is withdrawn.

Applicants amendment submitted November 15, 2006 with respect to the rejection of claims 9-12 under 35 USC 103 as being unpatentable over Burk in view of Bito further in view of Stand et al., of record in the previous office action, has been fully considered and found to be persuasive to remove the rejection as the ketone species which were found to be obvious over Burk in view of Bito are no longer included within the scope of the claims as amended. Therefore the rejection is withdrawn.

Applicants amendment submitted November 15, 2006 with respect to the rejection of claims 1-8 and 13-22 under 35 USC 103 as being unpatentable over Selliah in view of Silverman, of record in the previous office action, has been fully considered and found to be persuasive to remove the rejection as the ketone species which were

found to be obvious over Selliah in view of Silverman are no longer included within the scope of the claims as amended. Therefore the rejection is withdrawn.

Applicants amendment submitted November 15, 2006 with respect to the rejection of claims 1-8 and 13-22 under 35 USC 103 as being unpatentable over Selliah in view of Silverman, further in view of Stand et al., of record in the previous office action, has been fully considered and found to be persuasive to remove the rejection as the ketone species which were found to be obvious over Selliah in view of Silverman are no longer included within the scope of the claims as amended. Therefore the rejection is withdrawn.

Applicants amendment submitted November 15, 2006 with respect to the rejection of claims 1-8 and 13-22 under the judicially created doctrine of nonstatutory double patenting as being unpatentable over claims 1-13 of Burk in view of Bito, of record in the previous office action, has been fully considered and found to be persuasive to remove the rejection as the ketone species which were found to be unpatentable over Burk in view of Bito are no longer included within the scope of the claims as amended. Therefore the rejection is withdrawn.

Applicants amendment submitted November 15, 2006 with respect to the rejection of claims 9-12 under the judicially created doctrine of nonstatutory double patenting as being unpatentable over claims 1-13 of Burk in view of Bito further in view

Art Unit: 1623

of Stand et al., of record in the previous office action, has been fully considered and found to be persuasive to remove the rejection as the ketone species which were found to be unpatentable over Burk in view of Bito are no longer included within the scope of the claims as amended. Therefore the rejection is withdrawn.

Reasons for Allowance

Currently, claims 1-22 are pending in this application and have been examined on the merits herein. The claimed methods of treating ocular hypertension and compounds described in the instant claims, are not seen to be taught or fairly suggested by the prior art.

Reasons for allowance are as follows: The claimed prostaglandin derivatives and methods of using these compounds to treat ocular hypertension recited by the aforementioned claims are seen to be novel and non-obvious over the prior art and are directed to subject matter adequately described and enabled by Applicant's specification. Written description of the claimed compounds is found on pp. 7-9 of the instant specification, for example. Synthesis of these compounds is enabled by examples 1-8 on pp. 12-17. Methods of using these compounds for treating ocular hypertension are enabled by the disclosure of pp. 17-19. The most generic structures indicated in formula I, for example, are not taught or fairly suggested by the prior art. Although Burk (US patent 6291522, of record in the previous office action) discloses

Art Unit: 1623

prostaglandin F₂ derivatives of a formula similar to the claimed formula, and Burk in view of Bito (US patent 4599353, of record in the previous office action) discloses suggests prostaglandin E₂ derivatives of a similar structure, the prior art does not disclose prostaglandin derivatives having a halogen, such as chlorine, at the 5- position of the cyclopentane ring, or methods of using such compounds, or fairly suggest any motivation for modifying the compounds of Burk, or any other prior art compounds, in this manner. Therefore the indicated subject matter is allowable over the prior art.

Claims 21 and 22 have been amended in the examiner's amendment set forth above and no longer recite prostaglandin E₂ derivatives having a 5-oxo functional group which are unpatentable over Burk in view of Bito.

Accordingly, Applicant's amendment submitted November 15, 2006, and the accompanying examiner's amendment, are sufficient to remove all rejections made in the prior office action as discussed above and to place the application in condition for allowance.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

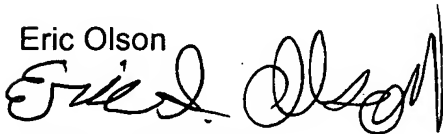
Art Unit: 1623

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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